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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/808,121

03/24/2004

Joseph S.M. Peiris

V9661.0069

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07/12/2006

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EXAMINER

MOSHER, MARY

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/808,121

Applicant(s)

PEIRIS ET AL.

Examiner

Mary E. Mosher, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2006 and 09 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 17, 18, 26-32, 101, 115, 117, 125, 135, 146, 165, 1-16, 20, 21, 23, 25, 54-56, 58, 60, 62, 75, 77, 79, 81, 89-100, 108-111, 121-124, 130-133, 135-139, 144, 151-154, 158-163, 166-173 is/are-pending in the application.

4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 18, 26-32, 101, 115, 117, 125, 135, 146 and 165 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/15/2004</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-16,20,21,23,25,54-56,58,60,62,75,77,79,81,89-100,108-111,121-124,130-133,135-139,144,151-154,158-163 and 166-173.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group II, species SEQ ID NO: 15 in the replies filed on 5/4/06 and 6/9/06 is acknowledged. Since SEQ ID NO:15 is the full-length genomic sequence of Strain HKU-39 strain SARS virus, the claims which correspond to this species are claims 17, 18, 26-32, 101, 115, 117, 125, 135, 146, 165.

Claims 1-16, 20, 21, 23, 25, 54-56, 58, 60, 62, 75, 77, 79, 81, 89-100, 108-111, 121-124, 130-133, 135-139, 144, 151-154, 158-163, 166-173 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group or species, there being no allowable generic or linking claim. Election was made **without** traverse in the replies filed on 5/4/06 and 6/9/06.

Priority; claim construction

As stated above, the elected species SEQ ID NO:15 is the full-length genomic sequence of Strain HKU-39 strain SARS virus. A full-length sequence was first disclosed in 60/464886, so the effective date for this species appears to be 6/23/2006. If the sequence (presented only in a figure) in 60/464886 is not the same as SEQ ID NO:15, please inform the examiner, because the date of first disclosure materially affects patentability in this application.

Some of the claims recited "hybridizes under stringent conditions". This term is defined on specification page 9 as meaning conditions in which nucleic acids having at least 70% identity hybridize.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

SEQ ID NO:15 appears to be free of the art. This sequence is identical to Genbank locus AY278491, version AY278491.2, GI 30023963. This appears to have been released on 29 August 2003, and is therefore unavailable as prior art. If applicants are aware of an earlier public release date for the sequence, please inform the examiner.

Therefore, search has been extended to determine if a generic claim is patentable.

Claims 18, 28, 31, 146 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention. SEQ ID NO:15 includes a poly-A tail. Therefore oligo-dT and oligo-U would hybridize to SEQ ID NO:15 under stringent conditions. Since these oligonucleotides have been in public use in this country for many years, the invention as claimed is not patentable.

Claims 17, 18, 26-32, 146 are rejected under 35 U.S.C. 102(a) as being anticipated by the TOR2 sequence, Genbank AY274119, version AY274119.1, GI 29826276 (14 April 2003). Please note, the website "SARS-associated Coronavirus" is cited as evidence that similar sequence data was publicly available 2 days earlier. Since

this sequence is more than 70% identical to SEQ ID NO:15, it clearly meets the limitations of the generic claims.

Claim Rejections - 35 USC § 112

Claims 101, 115, 117, 125, 135, 165 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims are drawn to pharmaceutical compositions comprising SEQ ID NO: 15. The specification does not teach how to use the full-length genomic sequence (or its complement) in any body-treating method, and its use seems inadvisable because it encodes a lethal virus. Considering the limited guidance in the specification and the state of the art, it is concluded that undue experimentation would be required to use the full-length SARS genomic sequence in body-treating compositions, as claimed.

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This claim is drawn to a nucleic acid which has at least 70% sequence match to part of SEQ ID NO:15 (or its complement), which encodes a polypeptide having a biological activity exhibited by any polypeptide encoded by SEQ ID NO: 15. However, at the time this application was filed, those skilled in the

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art were unsure what polypeptides were actually encoded by a SARS genome, or what biological activities were attributes of the putative polypeptides. See as evidence the publication by Sharma et al (Bioinformatics 20:1074-1080, May 1 2004, not prior art).

The specification teaches a 6-frame translation of SEQ ID NO:15, but teaches very little about the biological activity of any of the proteins and teaches nothing about what parts of the sequence can be altered while retaining the desired biological activity.

Considering the broad scope of the claim, the limited teachings of the specification, and the state of the art, it is concluded that the specification does not reasonably convey that applicants possessed the full scope of the invention as claimed.

Conclusion

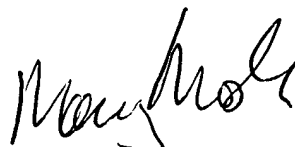
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

6/23/06


MARY E. MOSHER, PH.D.
PRIMARY EXAMINER